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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,877	09/18/2000	Song-Bae Kim	PM271427	3124

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EXAMINER
COE, SUSAN D

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/21/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/582,877	KIM, SONG-BAE	
	Examiner	Art Unit	
	Susan Coe	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The preliminary amendment filed June 30, 2000 has been received and entered.

2. Claims 1-8 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. Claims 1 and 5 are indefinite because the claims state that the both the Pulsatillae radix and Ulmaceae cortex can be present at 0%. Therefore, this composition does not have to contain any active ingredients. These claims are also indefinite because the claims do not define what are considered to be "conventional auxiliaries" and "conventional methods" of preparing a pharmaceutical. Therefore, the metes and bounds of the claims are unclear.

4. Claim 1 is indefinite because the number "60" has been split between lines 3 and 4 making it unclear what the extraction temperature must be.

5. Claims 2 and 6 are indefinite because it is unclear if each of the Pulsatillae radix and the Ulmaceae cortex are present at 30% or if the combination of the two equals 30%. In addition, the claim first states that these ingredients can be present at 0%. This conflicts with the limitation that requires each ingredient be present in a certain amount. The claims also specify that there is an additional ingredient selected from either Ginseng radix or Glycyrrhizae radix.

However, these ingredients can be present at 0%. Therefore, it is unclear if an additional ingredient is a required part of the composition. These claims are also indefinite due to the recitation of the word "ore" in line 4 of claim 2 and line 5 of claim 6. It is unclear if this a typographical error because this word does not make sense in the context of the claims. These claims are also indefinite because the claims do not define what are considered to be "conventional auxiliaries" and "conventional methods" of preparing a pharmaceutical. Therefore, the metes and bounds of the claims are unclear.

6. Claims 4 and 8 are indefinite because it is unclear what it meant by the term "indolent" in this context.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1 and 2 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,071,521. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims overlaps. Both the patented claims and the presently pending claims can

contain the same ingredients. The patented claims do not contain the process limitations found in the pending claims. However, the pending claims are still considered obvious over the patented claims because the process limitation in product-by-process claims are not considered to make the claim patentably distinct unless applicant can demonstrate a difference between the reference composition and the claimed composition.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 0 416 502 A1.

The reference discloses a composition which appears to be identical to the presently claimed composition, based on the fact that the both the reference composition and the claimed composition contain the same ingredients, i.e. extracts of Pulsatillae radix, Ulmaceae cortex, Ginseng, and Glycyrrhizae radix, and both have antitumor activity (see claims of EP '502). Consequently, the claimed composition appears to be anticipated by the reference.

However, even if the reference composition and the claimed composition are not the same and there is, in fact, no anticipation, the reference composition would, nevertheless, have rendered the claimed composition obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the clearly close relationship between the compositions as evidenced by their same ingredients and their shared antitumor activity. The reference does not specifically teach that the composition is lyophilized. However, in product-by-process claims, the process steps are only given patentable weight if applicant can demonstrate that the process limitations create a product that functions in an unexpectedly different manner from the reference composition.

Note that MPEP § 706.3(e) states that:

> "[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. In re Brown, 59 CCPA 1063, 173 USPQ 685 (1972) ; In re Fessmann, 180 USPQ 324 (CCPA1974)."

In addition, lyophilization is known in the art to be an effective means of either removing solvent after an extraction or processing the extracts for storage. Therefore, an artisan of ordinary skill would reasonably expect that the reference composition could be lyophilized. Thus, an artisan of ordinary skill would have been motivated to modify the reference composition to include lyophilization based on the benefits of lyophilization that are known in the art.

The reference also does not specifically teach adding the ingredients in all of the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary

skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

Claim Rejections - 35 USC § 103

9. Claims 5-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 416 502 A1.

EP '502 teaches a method of making a composition with antitumor activity by combining the extracts of Pulsatillae radix, Ulmaceae cortex, Ginseng, and Glycyrrhizae radix. The active ingredients are combined with diluents, binding agents, disintegrators, preservatives, and lubricants and are administered in various forms (see page 2, lines 1-5). The ingredients can be extracted using water and lower alcohols at a variety of temperatures (see lines 22-25). However, the reference does not specifically teach using all of the solvents claimed by applicant. The type of solvent used in an extraction is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal solvent to use in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the type of solvent used, this optimization of solvent type would have been obvious at the time of applicant's invention.

In addition, EP '502 does not teach lyophilizing the extracts. However, lyophilization is known in the art to be an effective means of either removing solvent after an extraction or processing the extracts for storage. Therefore, an artisan of ordinary skill would reasonably expect that the ingredients in the composition could be lyophilized. Thus, an artisan of ordinary skill would have been motivated to modify the process taught by EP '502 to include lyophilization based on the benefits of lyophilization that are known in the art.

The reference also does not specifically teach using the ingredients in all of the amounts claimed by applicant. The amount of a specific ingredient to use in making a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to use in making the composition in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
March 19, 2002

FRANCISCO PRATS
PRIMARY EXAMINER